Fresenius Medical Care

Fresenius COM.TEC Blood Cell Separator
510(k) Premarket Notification

SEP - 5 2006

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	95 Hayden Ave Lexington, MA 02420
Phone:	1-781-402-4475
Fax:	1-781- 402-9635
Contact Person:	Janet C. Kay, Sr. Regulatory Affairs Specialist
Date of Preparation:	March 9, 2006

B. Device Name:

Trade Name:	Fresenius COM.TEC Blood Cell Separator
Common/Usual Name:	Separator, Automated, Blood Cell, Diagnostic, Therapeutic
Classification Name:	Separator, Automated, Blood Cell, Diagnostic
Unclassified:	Separator, Automated, Blood Cell, Therapeutic

C. Predicate Device

The predicate devices for the Fresenius COM.TEC are the following:

- Fresenius AS104 Blood Cell Separator - #K895435 (11/02/90) and;
- Fresenius P1R Plasma Treatment Set for use in plasmapheresis - #K961706 (7/31/96).

D. Device Description/Indications for Use:

The intended use for the Fresenius COM.TEC blood cell separator is equivalent to that for the Fresenius AS104 blood cell separator, and is as follows:

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The COM.TEC Blood Cell Separator is a blood component separator, which utilizes centrifugal force as the basis of operation. The fields of application are as follows:

1. *Therapeutic plasma exchange - In plasmapheresis, the blood cell separator is used for the replacement of the blood plasma in the blood circuit by a plasma substitution solution or the reinfusion of the plasma after appropriate processing.*

2. *Therapeutic plasma therapy- In plasmapheresis therapy additional plasma treatment is performed through specific commercially available separation columns prior to return to the patient.*

E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius COM.TEC is a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the Fresenius COM.TEC is equivalent to that for the Fresenius AS104 and is as follows:

Intended Use - COM.TEC

The COM.TEC Blood Cell Separator is a blood component separator, which utilizes centrifugal force as the basis of operation. The fields of application are as follows:

1. Therapeutic plasma exchange - In plasmapheresis, the blood cell separator is used for the replacement of the blood plasma in the blood circuit by a plasma substitution solution or the reinfusion of the plasma after appropriate processing.

2. Therapeutic plasma therapy- In plasmapheresis therapy additional plasma treatment is performed through specific commercially available separation columns prior to return to the patient.

K060734

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Intended Use – Fresenius AS104

The Fresenius AS104 Cell Separator is intended for use in apheresis procedures involving donors and patients.

The fields of application are as follows:

- *Platelet collection*
- *Plasma exchange*
- *Granulocyte (polymorphlonuclear) cell removal*
- *Mononuclear cell removal*

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The features included in the Fresenius COM.TEC are equivalent to those present on the Fresenius AS104 and raise no new types of safety or effectiveness questions.

4. Does descriptive or performance information demonstrate equivalence?

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the COM.TEC and demonstrates that it is substantially equivalent to other commercially available Centrifugal Blood Cell Separators.

F. Safety Summary

The Fresenius COM.TEC blood cell separator has undergone rigorous software validation and performance testing, including clinical testing, software and hardware validation and verification, and biocompatibility testing of disposables. The results of this testing indicate that the Fresenius COM.TEC and associated disposables are safe and effective for their intended use and perform as expected.

G. General Safety and Effectiveness Concerns

The device labeling contains an Operator's Manual, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. This information promotes safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP - 5 2006

Ms. Janet C. Kay
Sr. Regulatory Affairs Specialist
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K060734
Trade/Device Name: COM.TEC Blood Cell Separator, TPE Set and P1R Set, for Therapeutic Plasma Exchange and Therapeutic Plasma Treatment
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: June 30, 2006
Received: July 3, 2006

Dear Ms. Kay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Fresenius Medical Care

Indications for Use

510(k) Number (if known): _____

Device Name: Fresenius COMTEC Blood Cell Separator

Indications for Use:

The COMTEC Blood Cell Separator is a blood component separator which utilizes centrifugal force as the basis of operation. The fields of application are as follows:

- plasma exchange
- plasma treatment

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060734

(Posted November 13, 2003)